UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

May 16, 2016

MEMORANDUM

Subject: Efficacy Review for CLB; EPA Reg. No. 5813-RRR; DP Barcode: D431529. E-Sub # 9408

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To: Srinivas Gowda / Demson Fuller, RM 32
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Applicant: The Clorox Company
c/o PS&RC
P.O. Box 493
Pleasanton, CA 94566-0803

Formulation from the Label:

Active Ingredient	% by wt.
Sodium Hypochlorite	6.0 %
Other Ingredients:	94.0 %
Total	100.0 %

(Yields 5.7% available chlorine)

I. BACKGROUND

The product, CLB (EPA File Symbol 5813-RRR), is a new product. The applicant requested to register the product as a disinfectant (bactericide, tuberculocide, fungicide, virucide), food-contact and non-food contact sanitizer, and deodorizer for use on hard, non-porous surfaces in household, schools, commercial, institutional, food preparation, animal care, and hospital or medical environments. The product will also be used as a laundry whitener and sanitizer. The product CLB is a new end use product with 6% sodium hypochlorite as the active ingredient. It is strongly related to Puma (8.25% sodium hypochlorite, EPA Reg. No. 5813-100), with the only main difference being the active ingredient concentration. The registrant approached the Agency regarding submitting an efficacy discussion comparing CLB's basic and alternate formulas to those of Puma registration in order to avoids costly duplicative efficacy testing as well as unnecessary micro-efficacy reviews.

This data package identified as D431529, contained a letter from the applicant to EPA (dated December 15, 2015), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), one study (MRID 496445-03), Statement of No Data Confidentiality Claims for the study, and the proposed label dated 12/15/15.

II. USE DIRECTIONS

The product is designed for disinfecting and sanitizing hard, non-porous surfaces. The product is also designed for use as a laundry sanitizer. The product may be used to treat hard, non-porous surfaces, including: appliances, baby bottles, baby toys, bathtubs, bicycles, bidets, brushes, car dashboards, car door handles, changing tables, combs, counter tops, crib bumpers, cutting boards, diaper pails, dishes, faucets, floors, flower pots, furniture, garbage cans, garbage disposals, glassware, golf balls and clubs, grills, handles, high chairs, litter boxes, lunchboxes, outdoor siding, painted cribs, patio furniture, pet bowls, plastic mattress covers, playground sets, play pens, pots and pans, shower curtains, shower doors, showers, sinks, sports equipment, steering wheels, thermometers, toilet bowls, toilets, toys, trash cans, trash compactors, urinals, utensils, wading pools, and walls. The label indicates that the product may be used on hard, non-porous surfaces, including: finished woodwork, glass, glazed porcelain, glazed tile, laminate, linoleum, painted woodwork, plastic (e.g., vinyl), sealed brick, sealed granite, sealed patio stone, stainless steel, and sealed stucco. The label indicates that the product is not for use on aluminum, chipped enamel, non-stainless steel, and silver.

III. BRIEF DESCRIPTION OF THE DATA

1. MRID 496445-03 "Supplemental Efficacy Discussion for CLB" for Puma, F2009.0092 by Julie Timberman. Study conducted at Clorox Pleasanton Campus. Study completion date – December 10, 2015.

This study was a data citation approach from to support the efficacy data requirements for CLB by citing efficacy data from Puma (EPA Reg. No. 5813-100). The Confidential Statement of Formula (CSF) for CLB is the same as Puma's basic CSF. CLB's alternate formula A01 is the same as Puma's alternate formula A19, except for a change in one of the ingredients' concentration (due only to raw material activity differences). Comparing end use dilutions, CLB's

“dose/concentration” combination is equal or exceeds Puma’s “dose/concentration” combination for every cited study.

IV. CONCLUSION

1. The CLB and Puma product formulations are essentially the same with the only difference being the sodium hypochlorite concentration. The CLB Basic Confidential Statement of Formula (CSF) matches the Puma Basic CSF in terms of inert ingredients and pH, and likewise the CLB alternate formula (CSF A01) matches the Puma alternate formula A19 (CSF A19). Because of the formula similarities, this product (CLB) may rely on the requested organisms (see MRID 49644503) performed with Puma (EPA Reg. No. 5813-100).

V. LABEL

1. The proposed end use dilutions of the product CLB (EPA File Symbol 5813-RRR) and its alternative formulation A01, **are acceptable** as they are the same or higher in active ingredient concentrations than the ones from Puma (EPA Reg. No. 5813-100) and its alternative formulation A19.

2. The applicant must make the following changes to the proposed label, as appropriate:

- On page 14, move the fruit and vegetable washing directions out of the "Sanitization Directions for Use" section. Also remove the term "sanitizing" from the fruit and vegetable washing directions.

- On page 20, remove the term “Common cause of respiratory infections” that is used to qualify Adenovirus type 2.

- On page 26, remove the references to produce/vegetable/fruit wash, soak or rinse since these uses do not belong under a sanitizing/disinfecting section.

- On page 26, remove the statement "disinfect[ing] [for] [the] [your] entire home" and "disinfects your home."

- On page 26, revise "helps prevent the spread…" to read "helps prevent the spread on treated surfaces…"